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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/075,053	STEVENS, ROBERT C.	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-24,26-41,43-61 and 63-65* is/are pending in the application.

4a) Of the above claim(s) *12-23 and 29-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-11, 24, 26-28, 41, 43-61, and 63-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al (U.S. Patent 5,951,539). Nita et al disclose a reinforced catheter having an elongate flexible tubular member (528) defining a lumen, a continuous coil reinforcement member (522) carried on the tubular member, a first flexible outer coating (546), and a second flexible outer coating (542). In lines 9-28 of column 9, Nita et al teach that the continuous coil reinforcement member extends from the proximal end of the catheter and terminates at the distal end of the catheter. In Figure 5, the coil reinforcement member terminates at the second or distal end of the catheter and Nita et al teach that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures where a distal nose tip section has been shown (see lines 7-11 of column 15). The catheter in Figure 10 is not specifically described as having a distal nose tip section and, therefore, this catheter is seen as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or

distal end of the catheter. In Figure 10, Nita et al show a first outer coating (546) which covers the coil reinforcement member and tubular member substantially entirely between the proximal end and the distal end of the catheter. A second outer coating (542) covers a first portion of the first outer coating between a transition area of the catheter and the proximal end of the catheter. A second portion of the first outer coating between the first transition area and the distal end of the catheter is uncovered by the second outer coating, thus defining a flexible distal tip. In lines 7-18 of column 16, Nita et al teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter. Figure 5 is similar to Figure 10 in that it shows a first outer coating (309) and a second outer coating as claimed. In lines 36-56 of column 14, Nita et al disclose the first outer coating at a distal section (246) of the catheter having a Shore hardness of about 40D and at a proximal section (240) of the catheter having a Shore hardness of about 70D. Thus, in the embodiment shown in Figure 10, when the first outer coating (546) has a Shore hardness of 40D, the material of the second outer coating (542) could be chosen to have a Shore hardness of 70D to provide additional stiffness in that proximal section as taught by Nita et al. The tubular member is formed of polytetrafluoroethylene (PFTE) (lines 34-39 of column 10) and the continuous coil reinforcement is a stainless steel wire and defines a helical pattern (lines 9-28 of column 9). In Figure 10, the distal end of the catheter is less than a thickness of the proximal end of the catheter. The first and second outer coatings may be made of a nylon or an urethane material (lines 19-35 of column 13). As to claim

24, the elongate flexible tubular member has a first end defining a lead end and a second end defining a trailing end and the continuous coil reinforcement member extends from the lead end to the trailing end. In Figure 14F, a continuous outer coating of a first material (572) covers the coil reinforcement member and the tubular member substantially entirely between the lead end and the trailing end. A continuous outer coating of a second material (590) covers the continuous outer coating of the first material (572) substantially entirely between the lead end and the trailing end. In line 65 of column 8 to line 7 of column 9, Nita et al teach that additional layers of polymeric material may be placed between the coil reinforcement member and the outer coating covering the reinforcement member. Additionally, in lines 16-18 of column 13, Nita et al teach that the polyethylene layer (which is the outermost layer or outer coating of the second material) may be left in place which is shown in Figure 14F. As to claim 26, Nita et al teach that the materials for the outer coatings may be chosen to have various values of Shore hardness, including the first material having a Shore hardness of 40D and the second material having a Shore hardness of 70D.

Even though Nita et al teach the first and second outer coatings substantially as claimed and further teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter, Nita et al are silent on the specifics of the first coating being softer than the second coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a harder material for the second coating of the catheter of Nita et al as Nita et al

teach choosing the material of the second coating so that the portion of the catheter with the second coating would be stiffer than the portion without the second coating. Furthermore, Nita et al teach using softer coatings on the distal portions of the catheter where more flexibility would be advantageous and using the harder coatings on the proximal sections to provide the desired stiffness to those sections. As to the specific hardness of the first and outer coatings, the parameter of hardness is deemed a matter of design choice (lacking in any criticality), well within the skill of ordinary artisan, obtained through routine experimentation in determining optimum results.

3. Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al in view of Landuyt (U.S. Patent Application Publication No. 2003/0109851). Nita et al disclose a reinforced catheter having an elongate flexible tubular member (528) defining a lumen, a continuous coil reinforcement member (522) carried on the tubular member, a first flexible outer coating (546), and a second flexible outer coating (542). In lines 9-28 of column 9, Nita et al teach that the continuous coil reinforcement member extends from the proximal end of the catheter and terminates at the distal end of the catheter. In Figure 5, the coil reinforcement member terminates at the second or distal end of the catheter and Nita et al teach that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures where a distal nose tip section has been shown (see lines 7-11 of column 15). The catheter in Figure 10 is not specifically described as having a distal nose tip section and, therefore, this catheter is seen

as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or distal end of the catheter. In Figure 10, Nita et al show a first outer coating (546) which covers the coil reinforcement member and tubular member substantially entirely between the proximal end and the distal end of the catheter. A second outer coating (542) covers a first portion of the first outer coating between a transition area of the catheter and the proximal end of the catheter. A second portion of the first outer coating between the first transition area and the distal end of the catheter is uncovered by the second outer coating, thus defining a flexible distal tip. In lines 7-18 of column 16, Nita et al teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter. Figure 5 is similar to Figure 10 in that it shows a first outer coating (309) and a second outer coating as claimed. In lines 36-56 of column 14, Nita et al disclose the first outer coating at a distal section (246) of the catheter having a Shore hardness of about 40D and at a proximal section (240) of the catheter having a Shore hardness of about 70D. Thus, in the embodiment shown in Figure 10, when the first outer coating (546) has a Shore hardness of 40D, the material of the second outer coating (542) could be chosen to have a Shore hardness of 70D to provide additional stiffness in that proximal section as taught by Nita et al. The tubular member is formed of polytetrafluoroethylene (PFTE) (lines 34-39 of column 10) and the continuous coil reinforcement is a stainless steel wire and defines a helical pattern (lines 9-28 of column 9). In Figure 10, the distal end of the catheter is less than a thickness of

the proximal end of the catheter. The first and second outer coatings may be made of a nylon or an urethane material (lines 19-35 of column 13). As to claim 24, the elongate flexible tubular member has a first end defining a lead end and a second end defining a trailing end and the continuous coil reinforcement member extends from the lead end to the trailing end. In Figure 14F, a continuous outer coating of a first material (572) covers the coil reinforcement member and the tubular member substantially entirely between the lead end and the trailing end. A continuous outer coating of a second material (590) covers the continuous outer coating of the first material (572) substantially entirely between the lead end and the trailing end. In line 65 of column 8 to line 7 of column 9, Nita et al teach that additional layers of polymeric material may be placed between the coil reinforcement member and the outer coating covering the reinforcement member. Additionally, in lines 16-18 of column 13, Nita et al teach that the polyethylene layer (which is the outermost layer or outer coating of the second material) may be left in place which is shown in Figure 14F. As to claim 26, Nita et al teach that the materials for the outer coatings may be chosen to have various values of Shore hardness, including the first material having a Shore hardness of 40D and the second material having a Shore hardness of 70D.

Even though Nita et al teach the first and second outer coatings substantially as claimed and further teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter, Nita et al are silent on the specifics of the first coating being softer than the second coating. Landuyt teaches a catheter having

a first coating (11) and a second coating (12) covering a first portion of the first coating between a first transition area of the catheter and the proximal end of the catheter. As seen in Figure 5, a second portion (5) of the first coating between the first transition area and the distal end of the catheter is uncovered by the second coating and defines a flexible distal tip. Landuyt teach that the first coating (11) is softer than the second coating (12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the first coating of Nita et al to be softer than the second coating as taught by Landuyt as both Nita et al and Landuyt disclose that it is desirable to have the proximal portion of the catheter be more stiffer than the distal portion and Landuyt teach the use of a harder material for the second coating to achieve the desired stiffness while still maintaining a softer distal portion. As to the specific hardness of the first and outer coatings, the parameter of hardness is deemed a matter of design choice (lacking in any criticality), well within the skill of ordinary artisan, obtained through routine experimentation in determining optimum results.

4. Claims 4, 5, 44, 45, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al as applied to claims 1, 41, and 52 above, and further in view of Follmer et al (U.S. Patent No. 5,728,065). Nita et al disclose the catheter substantially as claimed. Even though Nita et al teach (in lines 21-31 of column 18) that it is desirable to use a platinum radio-opaque or marker band adjacent the distal end of the catheter (506 in Figure 8, 534 in Figure 9), Nita et al are silent on the specifics of the marker being disposed on the outer

coating. Follmer et al teach a marker band (124) disposed adjacent the distal end of the catcher on the outer coating in the same field of endeavor of reinforced catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the marker band of Nita et al on the outer coating as taught by Follmer et al as both Nita et al and Follmer et al teach that it is desirable to provide catheters with marker bands and Follmer et al teach that the marker bands can be placed on the outer coating of the catheter.

5. Claims 4, 5, 44, 45, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al in view of Landuyt as applied to claims 1, 41, and 52 above, and further in view of Follmer et al (U.S. Patent No. 5,728,065). Nita et al disclose the catheter substantially as claimed. Even though Nita et al teach (in lines 21-31 of column 18) that it is desirable to use a platinum radio-opaque or marker band adjacent the distal end of the catheter (506 in Figure 8, 534 in Figure 9), Nita et al are silent on the specifics of the marker being disposed on the outer coating. Follmer et al teach a marker band (124) disposed adjacent the distal end of the catcher on the outer coating in the same field of endeavor of reinforced catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the marker band of Nita et al on the outer coating as taught by Follmer et al as both Nita et al and Follmer et al teach that it is desirable to provide catheters with marker bands and Follmer et al teach that the marker bands can be placed on the outer coating of the catheter.

Response to Arguments

6. Applicant's arguments filed April 19 2007 have been fully considered but they are not persuasive.

Applicant's arguments in line 4 of page 16 to line 2 of page 17 regarding the continuous coil reinforcement member are not persuasive because Nita et al specifically teach that a distal nose tip or bumper tip may not be present on the catheters disclosed and as shown in the figures. Specifically, in lines 7-11 of column 15, Nita et al teach that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures where a distal nose tip section has been shown. "Use of layers of coil in excess of the preferred dual layer distal-to-proximal layers is a feature independent of the presence or absence of other features, e.g., the distal nose tip section" (lines 7-11 of column 15) can be interpreted to mean that a distal nose tip section may be absent. Applicant's arguments with respect to the specification of Nita et al beginning at line 65 of column 15 where Nita et al indicate the presence of a bumper tip are also not persuasive. If Nita et al do intend to include the presence of a bumper tip in each of the embodiments, then the distal most portion of the catheter as seen in Figures 7, 11, and 12 would be considered to have a bumper tip. However, in these embodiments, the coil reinforcement member is seen to extend from the proximal end of the catheter and terminate at the second end of the tubular member where the second end of the tubular member defines a distal end of the catheter. With respect to the embodiment shown in Figure 10, the distal end of the catheter is not shown but the distal end shown in Figure 7 is a

variation of a distal end of the catheter. Therefore, it can be seen that a distal end as shown in Figure 7 where the coil reinforcement member terminates at the second end of the tubular member would be a reasonable distal end for the catheter shown in Figure 10. Therefore, even with the presence of the "bumper tip", the coil reinforcement member of Nita et al is seen to extend from the proximal end of the catheter and terminate at the second or distal end of the catheter as claimed. Furthermore, Nita et al teach that the bumper tip has a negligible effect on the operation of the catheter other than to protect the arteries from potential damage by the coil reinforcement member. It should be noted that Nita et al also disclose the coil reinforcement member extending from the proximal end of the catheter and terminating at the second end of the tubular member where the second end of the tubular member defines a distal end of the catheter in lines 13-17 of column 9, in lines 39-44 of column 15, and in lines 13-23 of column 19.

Applicant's arguments regarding the first coating being softer than the second coating in lines 10-16 of page 18 are not persuasive because Nita et al do teach, with respect to Figure 10, that the material of the second coating (542) would be chosen such that it would provide additional stiffness to the proximal section of the catheter. Also, Nita et al do teach using softer coatings on the more distal portions of the catheter to give the distal portion more flexibility. Therefore, a harder material for the second coating would give the proximal section of the catheter more stiffness which Nita et al teach is desirable.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

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